Life Science Contamination Control Forum

The Latham Hotel Washington, DC

February 11-13, 2003

"FNSURE BIOBURDEN CONTROL

through efficient design models and carefully planned operational procedures."

Laboratory research and manufacturing depends on contaminant-free facilities and safe environments for both personnel and product.

ASHRAE member discount, see registration page for details.

Two Track Conference Program:

Track One — Design and Engineering of Cleanroom Environments

- Understanding cGMPs for contamination controlled environments
- Reducing risk of cross-contamination
- Design considerations cost-effective approaches and future flexibility
- Designing efficient air handling systems and maintaining bioburden control
- Biological safety cabinets construction and safety considerations

Track Two — Personnel Management and Operation within Controlled Environments

- Controlling bioburden when introducing humans into cleanroom environments
- Environmental monitoring and validation of cleanroom management practices
- Personnel protection from potent compounds
- Implementing control and safety practices gloving, gowning, entry, behavior
- Cleaning issues and approaches

Pre-Conference Workshop — February 11, 2003:

1:00pm - 5:00pm

The Cleanroom for Life Sciences – Exploring the Essentials

Moderated by: AnneMarie Dixon

Cleanroom Management Associates, Inc.

Media Partners:





Perspectives From Industry Leadership:

Cleanroom Management Associates, Inc.,

AnneMarie Dixon - WG Leader, IEST

Cleanroom Consulting, LLC, Scott Mackler

Eli Lilly and Company, Gary Bird

National Institutes of Health (NIH), Frank Kutlak

Baxter Corporation, Thomas Barber

Cintas Cleanroom Resources, Jan Eudy – Technical Vice President, IEST

Elan Pharmaceuticals, Greg Andert

Genentech, Carole Genovesi

Pfizer Global Research & Development, Robert Sussman, Ph.D.

Technovations Systems, Inc., Raj Jaisinghani

Safebridge Consultants, Inc., Allan Ader, Ph.D., DABT

Ardmac, Conor Murray - Chairman, Irish Cleanroom Society

Eastern Research Group/Labs21, Chris Benjamin

Chiron Corporation, Jeff Regnier

Filtration Group, Gene Klingbeil

Milliken & Company, Creighton Kelly – WG Leader, IEST

BFK Solutions, Barbara Kanegsberg

AdvanceTec, Tim Loughran

Baker Co., Dave Stuart, Ph.D.

Dycem, Tom Mulligan

Rytec Corporation, Don Grasso

Further Industry Information:





Schedule-At-A-Glance

Pre-Co	nference Workshop — Tuesday, February 11, 2003			
1:00				
1:30	Pre-Conference Workshop — The Cleanroom for Life Sciences – Exploring the Essentials			
5:00	Conclusion of Workshop			
Day Or	ne — Wednesday, February 12, 2003			
8:00	Registration and Continental Breakfast			
8:45	Opening Remarks from the Conference Chair			
9:00	Panel Session – Industry Initiatives in Standards Compliance			
10:00	<u> </u>			
	TRACK ONE — Design and Engineering of Cleanroom Environments	TRACK TWO — Personnel and Operations Management		
10:30	Opening Remarks from Section Chair	Opening Remarks from Section Chair		
10:45	Applying Pharmaceutical cGMPs for Contamination Controlled Environments	Maintaining Contamination Control when Introducing		
		Humans into Cleanroom Environments		
11:30	Modular Concepts in Design Build	Regulatory Compliance for Contamination-Controlled		
		Manufacturing Environments		
12:15	Luncheon for Delegates and Speakers			
1:30	Reducing Cross-Contamination Risk in Life Science Cleanrooms	Controlling Bioburden in Life Science Cleanroom Environments		
2:15	Energy Efficient Laboratory Design –	Environmental Monitoring of Cleanrooms		
	The Louis Stokes Laboratories – NIH Building 50			
3:00	Afternoon Refreshments			
3:30	Cleanroom Refurbishing – Cost-Effective Planning for Future Applications	Validation of Microbial Air Sampling		
4:15	Laboratories for the 21st Century –	Approaches to Room Decontamination		
	Improving the Performance of US Laboratories			
5:00	Roundtable Sessions — GMPs, Design Approaches and Federal Regulations	Roundtable Sessions — Environmental Monitoring of Cleanrooms		
	for Clearoom Consutruction			
5:45	End of [Day One		
	o — Thursday, February 13, 2003			
8:00	Registration and Continental Breakfast			
0.45	TRACK ONE — Design and Engineering of Cleanroom Environments	TRACK TWO — Personnel and Operations Management		
8:45	Opening Remarks from Section Chair	Opening Remarks from Section Chair		
9:00	State of the Art Airflow Design in Cleanrooms and Control	Personnel Protection from Potent Compounds		
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10:00	Maurica D	Health-Based Containment Approaches to Surface-Level Potent Compounds		
10:30	Morning Refreshments			
11:00	Controlling Airborne Particulate and Associated Risk –	Implementing Control and Safety Practices within Cleanroom		
11.45	A CDC Laboratory Case Study Filtration Models for Controlled Environments			
11:45		nates and Charles		
12:30		Luncheon for Delegates and Speakers		
1:45 2:30	Validation of Airflow Systems Biological Safety Cabinets	Cleaning Issues and Approaches		
3:15	· ·			
3:15	Afternoon Refreshments			
4:15	Flooring Approaches to Reduction of Foot-Borne Contamination	Roundtable Sessions — Toxicological Risk Assessment, Personnel Managemen		
5:00	Roundtable Sessions — HVAC, Filtration and Air Handling Systems Conclusion of Conference			
5:00	Conclusion of Conference			

Pre-Conference Workshop — Tuesday, February 11, 2003

1:00 Registration

1:30 Pre-Conference Workshop

The Cleanroom for Life Sciences – Exploring the Essentials

Within pharmaceutical, biotechnology and medical research organizations, the cleanroom concept means unique requirements, careful planning and design, compliance with federal regulations, and proper training for safety assurance. This opening workshop will explore the basics of contamination, and why the life science industry should be so concerned. What is a cleanroom? Where does contamination come from? Case histories will be applied to show consideration for all relevant contamination control issues:

- Awareness of federal regulations
- Sterility concerns for the life sciences
- Systems design and engineering
- Ongoing management and personnel approaches
- Standards and compliance monitoring

Facilitator: AnneMarie Dixon

Cleanroom Management Associates, Inc.

Working Group Leader, Institute of Environmental Sciences and Technology (IEST)

5:00 Conclusion of Workshop

Day One — Wednesday, February 12, 2003

8:00 Registration and Continental Breakfast

8:45 Opening Remarks from the Conference Chair

9:00 Joint Panel Session

Industry Initiatives in Standards Compliance

Maintaining a contamination controlled environment starts with an understanding of federal regulations. This session will explore standards developments, including ISO 14644, and their impact on cleanroom environments. As organizations take on new efforts to maintain levels of safety, this session is designed to offer perspectives on current federal requirements, areas for concern and continued improvement.

Panelists:

Gary Bird, Senior Regulatory Consultant, Eli Lilly and Company

Jan Eudy, Corporate Quality Assurance Manager, Cintas Cleanroom Resources

Technical Vice President – Contamination Control Division, Institute of Environmental Sciences and Technology (IEST)

10:00 Morning Refreshments

Conference Sessions Break into Two Focused Tracks

TRACK ONE SESSIONS — Design and Engineering of Cleanroom Environments

Section A — Concepts in Room Design

10:30

Opening Remarks from Section Chair

Scott Mackler, Principal Consultant Cleanroom Consulting, LLC

10:45

Applying Pharmaceutical cGMPs for Contamination Controlled Environments

Design of building and equipment rely heavily on cGMPs, as well as careful evaluation of functional requirements and intended applications. This session will consider cGMPs, as well as operational procedures for continued upkeep of facilities.

- Recommended practices and international standards for cleanroom design
- Risk management and product quality considerations
- Advancements in life science contamination control applications impact on cGMP's
 - Impact of scientific progress gene therapy, tissue therapy, etc.

Scott Mackler, Principal Consultant

Cleanroom Consulting, LLC

11:30

Modular Concepts in Design Build

- Regulatory compliance and health and safety drivers
- Industry trends to meet 'time to market' and 'time to change' drivers
- Designing for optimum validation
 - Design qualification
 - Installation qualification
 - Operational qualification
- Converting performance obligations into acceptance tests
- Understanding FDA and EU regulatory guidelines and impact on airflow and HVAC models
- Architectural product selection
- Clean build protocols and construction techniques
- Commissioning and qualification issues
- Principles for controlling costs

Conor Murray, Technical Director Ardmac, Ltd.

Founder and Chairman, Irish Cleanrooms Society

12:15 Luncheon for Delegates and Speakers

1:30

Reducing Cross-Contamination Risk in Life Science Cleanrooms

- Identifying sources of cross-contamination
 - Cleanroom entry points
 - Doors
 - Exhaust fans and air handling systems
 - Tools and equipment
- Approaches to minimize cross-contamination
 - Doors high speed doors
 - HVAC approaches
 - Equipment sterility
 - Personnel practices

Don Grasso, President and Chief Executive Officer **Rytec Corporation**

2:15

Energy Efficient Laboratory Design – The Louis Stokes Laboratories – NIH Building 50

The Louis Stokes Laboratories, Building 50, located at the National Institutes of Health (NIH) in Bethesda, MD, is a joint endeavor of the US EPA and the US DOE. The laboratories, which include several specialized biosafety areas, were completed for occupancy in April 2001. This session will explore the energy-efficient design and engineering of Building 50. Utilizing desiccant energy recovery heat wheels and VAV supply and exhaust systems, the lab consumes 40% less energy than a traditional research facility. Frank Kutlak, Architect and Project Officer the Building 50 project will examine the energy demands on laboratory buildings and offer feasible solutions to minimize energy consumption.

Frank Kutlak, Architect and Project Officer National Institutes of Health (NIH)

3:00 Afternoon Refreshments

3:30

Cleanroom Refurbishing – Cost-Effective Planning for Future Applications

- Maintaining flexibility in design models for future projects
- Considerations with systems and components
 - Lighting
 - Airflow
 - Components
- Budgetary models and considerations of project worthiness
 - Front-end intelligence of future applications
 - Demanding flexibility from suppliers
- Risk management awareness for refurbished cleanroom environments
 - Ensuring process integrity and product quality

Tim Loughran, Managing Partner **AdvanceTec**

TRACK ONE SESSIONS — Design and Engineering of Cleanroom Environments

Laboratories for the 21st Century — Improving the Performance of US Laboratories

Labs21 is a joint US program designed to improve the performance of US laboratories. This session will outline the components of the program, discuss the environmental and economic benefits for participants, and identify the various ways organizations can become involved. Labs21 currently focuses on improving laboratory energy and water efficiency, encouraging the use of renewable energy sources, and promoting environmental stewardship. The program consists of three components: establishing voluntary partnerships with public agencies and private corporations, offering educational and training opportunities, and developing tools to facilitate innovative laboratory design and operation. Labs21 is also working to support lab-intensive industry sectors such as pharmaceutical and biocontainment laboratories. Tools include a criteria for evaluation the environmental performance of laboratories, benchmarking energy performance, case studies of high performance labs, and an interactive laboratory design guide.

Chris Benjamin

Eastern Research Group

Principal Contractor, US EPA and Labs21

5:00 Roundtable Sessions

Roundtable Theme — GMPs, Design approaches and Federal Regulations for Cleanroom Construction

At the conclusion of each conference day, participants will have the opportunity to review concepts addressed during the day's sessions, but in an informal, discussion-based environment. Small settings will allow for delegates to pose questions to speakers or other attendees and exchange ideas, comments, etc. These roundtables will be lead by speakers from previous sessions to ensure interactive discussion in a comfortable setting.

5:45 Conclusion of Day One — Track One Sessions

TRACK TWO SESSIONS — Personnel and Operations Management

Section D — Operational Aspects of Controlled Environments

10:30

4:15

Opening Remarks from Section Chair

Jeff Regnier, Director – Environmental Health and Safety Chiron Corporation

10:45

Maintaining Contamination Control when Introducing Humans into Cleanroom Environments

While a heavy emphasis placed upon the design and engineering of cleanroom areas, human involvement is the primary source of contamination. Technology and systems design is important, but irrelevant without careful monitoring of human behavior. This session will explore the importance of personnel management, its necessary position within the corporate culture, and the long-term payoff of sound personnel safety procedures.

Jeff Regnier, Director – Environmental Health and Safety Chiron Corporation

11:30

Regulatory Compliance for Contamination-Controlled Manufacturing Environments

- FDA requirements
- Contamination specifications
 - Materials
 - Equipment and components
 - Products
- Preventing contamination
 - Personnel approaches to contamination control
 - Training programs
 - Aseptic precautions
 - Gowning procedures

VecTech Pharmaceutical Consultants

12:15 Luncheon for Delegates and Speakers

1:30

Controlling Bioburden in Life Science Cleanroom Environments

- Monitoring airborne and process-level particulate
- Measurement approaches
- Real-time particulate monitoring with UV fluorescence

Carole Genovesi, Manager – Environmental Quality Control Genentech

2:15

Environmental Monitoring of Cleanrooms

- Implementing environmental monitoring programs for sterility maintenance
- Developing an environmental monitoring program
- Monitoring and validation of cleanrooms
- FDA considerations
 - HEPA/ULPA filters
 - Airflow velocities
 - Water testing

Thomas Barber, Senior Director – Particle Sciences **Baxter Healthcare, Inc.**

3:00 Afternoon Refreshments

3:30

Validation of Microbial Air Sampling

- Factors in consideration of collection approaches
 - Design specifics of cleanroom
 - Flow rates
- Determining the ideal sampling approach
 - Aerosol collection
 - Anisokinetic collection

Speaker TBA

4:15

Approaches to Room Decontamination

- Evaluating the effectiveness of anti-microbial wipes
- Alternate decontamination approaches and advantages/disadvantages
- Sterilization strategies and Sterility Assurance Levels (SALs)

Creighton Kelly
Milliken & Company

Working Group Leader, Institute of Environmental Sciences and Technology (IEST)

5:00

Roundtable Sessions

Roundtable Theme — Environmental Monitoring of Cleanrooms

At the conclusion of each conference day, participants will have the opportunity to review concepts addressed during the day's sessions, but in an informal, discussion-based environment. Small settings will allow for delegates to pose questions to speakers or other attendees and exchange ideas, comments, etc. These roundtables will be lead by speakers from previous sessions to ensure interactive discussion in a comfortable setting.

5:45 Conclusion of Day One — Track Two Sessions

Registration and Continental Breakfast

Conference Sessions Break into Two Focused Tracks

TRACK ONE SESSIONS — Design and Engineering of Cleanroom Environments

Section B — Air Handling and HVAC Concepts

8:45

Opening Remarks from Section Chair

Raj Jaisinghani, President

Technovation Systems, Inc.

9:00

State of the Art Airflow Design in Cleanrooms and Control of Airborne Bioburden

Air handling design is the most important variable affecting the performance of cleanrooms – and initial and operating costs. This session will examine airflow design methods and present technical models for rational design of airflow. It will be argued that scientific and engineering models need to be developed to meet current industry requirements in a more cost-effective manner. Special emphasis will be applied to energy and operating costs. Examples of performance and actual savings in cleanroom projects will also be provided. Control methods for airborne and surface bioburden will also be presented with field data from a biotech facility using a bactericidal HEPA filtration system. Questions will be raised as to whether or not airflow velocity, initial costs and operating costs can be lowered, while ensuring FDA compliance and maintaining bioburden control.

Raj Jaisinghani, President

Technovations Systems, Inc.

10:30 Morning Refreshments

11:00

Controlling Airborne Particulate and Associated Risk – A CDC Laboratory Case Study

- Allowable particulate levels for the life sciences industry
- FDA and GMP regulations in consideration of HVAC design
- Air distribution models
 - Direct vs. plenum air-flow models
 - Positive vs. negative (reverse-flow) flow models
- Maintaining humidity levels appropriate to control of viable and non-viable particulate
- Considerations of spatial configurations
- Intended applications
- Understanding intended applications and integrating flexibility for future renovations

Speaker TBA

11:45

Filtration Models for Controlled Environments

- HEPA/ULPA systems design for the controlled environment
 - Filter types and basic usage
- Filter designs and construction
 - Filter construction techniques
 - Pleat geometry/media surface area
 - Pleat precision and uniformity
 - Importance of laminar airflow
 - Energy efficiency vs. filter restriction
- Testing high efficiency filters
 - Importance of testing and types of testing required
- Effectiveness of filter particle removal
 - Particle collection mechanisms
 - Most Penetrating Particle Size (MPPS)
 - Controlling micro-organisms
 - Reducing risk at filters
- Effects of moisture and temperature on filters
 - Microbial growth vs. efficiency
 - Effects of relative humidity and temperature

Gene Klingbeil, Product Manager

Filtration Group, Inc.

12:30 Luncheon for Delegates and Speakers

1:45

Validation of Airflow Systems

- Establishing maintenance procedures and requirements
- Monitoring air quality testing of viable and non-viable particles
- Training and procedures for operating personnel
- Over-validation and impact on production times and quality

Gregory Andert, Associate Director – Maintenance and Engineering **Elan Pharmaceuticals**

Section C — Components and Additional Considerations

2·30

Biological Safety Cabinets

- Construction of BSCs
- Consideration of applications and safety considerations
 - Evaluation of design alternatives
 - Biological safety cabinets
 - Clean benches
 - Fume hoods
 - Glove boxes
- Biosafety levels identifying the appropriate cabinet type for specific applications
- Microbiological aerosol tests
 - Considerations for human and product protection
- Airflow models in BSCs
- Exhaust biological safety cabinets
- Decontamination of BSCs

Dave Stuart, Ph.D., Microbiologist **The Baker Co.**

3:15 Afternoon Refreshments

3:30

Flooring Approaches to Reduction of Foot-Borne Contamination

- Foot-borne contamination as a source of viable particles
- Approaches to reduction of foot-borne contaminants
 - Peel-off mats
 - Polymeric flooring
- Effectiveness in reducing viable and non-viable particles
- Importance of equipment and procedures viewing flooring as an additional precaution

Tom Mulligan, President of American Operations **Dycem**

4:15

Roundtable Sessions

Roundtable Theme — HVAC, Filtration and Air Handling Systems

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5:00 Conclusion of Track One Sessions

TRACK TWO SESSIONS — Personnel and Operations Management

8:45

Opening Remarks from Section Chair

Allan W. Ader, Ph.D., DABT, Principal Toxicologist SafeBridge Consultants, Inc.

9:00

Personnel Protection from Potent Compounds

As products become more potent and more effective for patients, the risk scientists incur in manufacturing processes becomes greater. Risk management strategies are integral to facility design, and procedures to protect employees must be carefully developed.

- Exposure control strategies and development of risk management programs
 - Toxicology assessments
 - Dealing with unknown toxicity levels (R&D stages)
 - Quantifying risk
 - Occupational exposure bands
 - Occupational exposure limits

Robert Sussman, Ph.D., Director – Toxicology and Hazard Assessment Pfizer Global Research and Development

10:00

Health-Based Containment Approaches to Surface-Level Potent Compounds

- Acceptable surface limits for occupational health purposes
- Potent compound containment approaches

Allan W. Ader, Ph.D., DABT, Principal Toxicologist SafeBridge Consultants, Inc.

10:30 Morning Refreshments

11:00

Implementing Control and Safety Practices within Cleanroom

This session will focus on the importance of safety programs and strategies for implementation. Critical points of discussion will include development and management of policies, equipment involved and behavioral practices for controlled environments.

- Handwashing, gloving, gowning
- Entering the cleanroom, behavior in the cleanroom, exiting the cleanroom
- Design and engineering considerations of laboratory environments and impact of safety measures

Jan Eudy, Corporate Quality Assurance Manager

Cintas Cleanroom Resources

Technical Vice President, Institute of Environmental Sciences

and Technology (IEST)

12:30 Luncheon for Delegates and Speakers

1:45

Cleaning Issues and Approaches

- Cleaning systems and environmental regulatory measures
 - Solvents and agents for precision cleaning
 - Environmental drivers and safety measures
- How clean is clean measuring levels of cleanliness
- Surface preparation and cleanliness
- Particle removal
- Employee awareness and staff training programs
- Understanding the "why's" of all procedures

Barbara Kanegsberg, President **BFK Solutions**, **Inc.**

3:15 Afternoon Refreshments

3:30

Roundtable Theme — Toxicological Risk Assessment Personnel Management

At the conclusion of each conference day, participants will have the opportunity to review concepts addressed during the day's sessions, but in an informal, discussion-based environment. Small settings will allow for delegates to pose questions to speakers or other attendees and exchange ideas, comments, etc. These roundtables will be lead by speakers from previous sessions to ensure interactive discussion in a comfortable setting.

Roundtable Sessions

5:00 Conclusion of Track Two Sessions

Who Should Attend: This unique program has been designed to address contamination control approaches specific to pharmaceutical, biotechnology and medical research organizations. Critical aspects of cleanroom development, including design and engineering, standards compliance, personnel practices, and training and administration approaches will be discussed. Conference content has been divided into two primary tracks, allowing for focused discussion.

Track One — Design and Engineering of Controlled Environments

Intended for: Directors of Operations, Facility and Safety Engineers, Design Engineers, Project Managers

Track Two — Personnel Management and Operation with Controlled Environments

Intended for: Laboratory Practitioners, Microbiologists, Safety and Quality Assurance Managers, Environmental Monitoring Specialists

Program attendees will have the opportunity to hear discussions from both conference tracks. Documentation from all sessions to be provided to conference attendees

Business Opportunities: A limited amount of exhibition space is available at the conference. A variety of sponsorship opportunities covering luncheon, evening functions, and documentation also exist. For further details, contact Michael Robinson, General Manager at 312 894 6375 or michaelr@marcusevansch.com.

www.meLifeSciences.com

Please write in **BLOCK CAPITALS**

Registration Contract	Conference:	Life Science Contamination Control Forum
Please complete this form immediately and fax back to:	Date(s):	February 11-13, 2003
Fax: 312 894 6390 For further information call 312 894 6418	Location:	The Latham Hotel 3000 M St. NW Washington, DC 20007 Ph: 202 726 5000
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Phone: Fax:	terms are five day	ys and payment must be made prior to the start of the conference. No
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Nature of Business:		o mitigate its losses for any less than 50% of the total contract value.
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